investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product GEMZAR® (gemcitabine hydrochloride). GEMZAR® is indicated for use as a firstline treatment for patients with locally advanced (nonresectable stage II or stage III) or metastatic (stage IV) adenocarcinoma of the pancreas in patients previously treated with 5–FU. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GEMZAR® (U.S. Patent No. 4,808,614) from Eli Lilly & Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 7, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of GEMZAR® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for GEMZAR® is 3,293 days. Of this time, 2,824 days occurred during the testing phase of the regulatory review period, 469 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: May 12, 1987. The applicant claims June 18, 1987, as the date the investigational new drug application (IND) for GEMZAR® became effective. However, FDA records indicate that the IND effective date was May 12, 1987, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: February 2, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for GEMZAR® (NDA 20–509) was initially submitted on February 2, 1995.

3. *The date the application was approved:* May 15, 1996. FDA has verified the applicant's claim that NDA 20–509 was approved on May 15, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,537 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 2, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 1, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–20593 Filed 7–31–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

District Consumer Forum; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration's (FDA's), Office of Consumer Affairs (OCA) the Office of Regulatory Affairs (ORA) offices in Illinois, Michigan, and Indiana in cooperation with the U.S. Dept. of Health and Human Services Office of Minority Health, Office of Public Health Sciences, Region V, Illinois Department of Public Health, Center for Minority Health Services and Asian Health Coalition of Illinois, Chicago Department of Health, Chicago Hispanic Health Coalition, U. S. Department of Agriculture Food and Nutrition Service, Regional Office, Midwest Field Office, Health Resources and Services Administration, and the University of Illinois Extension Chicago Cooperative Extension Center is announcing a district consumer forum. The forum will provide an opportunity for consumers, community-based organizations, patient advocates, health professionals, and industry to participate in open discussions on health issues and agency regulatory actions with FDA officials.

Date and Time: The forum will be held on Tuesday, August 18, 1998, from 10 a.m. to 1 p.m.

Location: The forum will be held at the Sears Tower, 233 South Wacker Dr., Lincoln Ballroom, 33d Fl., Chicago, IL 60606.

Contact: Kimberly Phillips, Chicago District Office, Office of Regulatory Affairs, 300 South Riverside Plaza, suite 550–South, Chicago, IL 60606, 312–353–7126, FAX 312–886–3280.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by August 10, 1998. Every effort will be made to accommodate all registrants. However because space is limited, admittance is on a ''first come, first serve basis.''

If you need special accommodations due to a disability, please contact Kimberly Phillips (address above) by August 10, 1998.

Transcripts: Transcripts of the forum may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the forum, at a cost of 10 cents per page.

Dated: July 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20595 Filed 7–31–98; 8:45 am]

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